Attorney Docket No.: 560

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	AVRAMOFF et al	GROUP NO.:	1618
SERIAL NUMBER:	10/575,809	CONFIRMATION NO:	5244
FILING DATE:	13 April 2006	EXAMINER:	WESTEBERG, Nissa M

TITLE: STABLE LANSOPRAZOLE FORMULATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF CONFERENCE REQUEST

Sir:

This paper is responsive to the Office Action mailed from the U.S. Patent and Trademark Office on November 23, 2009 and is timely being filed on or before February 23, 2010.

Applicant hereby requests a Pre-Appeal Brief Conference as the current claims have been rejected twice, yet the rejections were not supported by specific citations in any art references. Applicant held an Interview with the Examiner, in which these assertions of Applicant were discussed but no agreement was reached with the Examiner.

Applicant has below provided a list of those claims in which Applicant feels that a clear error was made; however, Applicant reserves the right to expand the arguments to cover the remaining claims and/or to provide additional arguments for these claims if an Appeal Brief is filed.

Brief Overview of the Claims

The claims cover a method for administering lansoprazole, comprising administering a composition comprising a substrate comprising lansoprazole as sole pharmaceutically active agent, wherein the substrate does not include an alkaline agent; a

subcoating layer comprising sodium stearate as an alkaline agent; and an enteric layer over the subcoating layer.

Rejections Under 35 U.S.C. §103

Applicant has received multiple rejections for the claims of the above application relating to the inclusion of an alkaline agent in the subcoating layer. According to the Examiner, the use of sodium stearate as alkalinizing agent in the subcoating layer is obvious in view of prior art teachings of use of magnesium stearate in a subcoating layer. Applicant maintains that sodium stearate and magnesium stearate are entirely different materials, and has repeatedly argued the functional differences between the two.

1. In an Office Action dated June 23, 2008, the Examiner cited Depui WO 96/24375 with regard to novelty, and Depui '375 alone and further in view of Lundberg EP 1174136, Edgren US 6,210,712 or Depui US 2002/0155153 with regard to obviousness.

Following a personal interview with the Examiner in Sept 2008, Applicant submitted a response in which it was argued that the characterizing feature of the formulation of the present invention is that the substrate is devoid of an alkaline agent while an alkaline agent is provided in the separating layer. In contrast, Depui '375 teaches a formulation in which the inclusion of an alkaline substance in the core is optional, and not a characterizing feature.

The Examiner referred to specific examples of Depui '375 which included magnesium stearate in the subcoating layer, and which the Examiner referred to as an alkaline agent. However, as stated in Applicant's response, magnesium stearate is referred to in the '375 specification as an example of an additive such as a plasticizer, colorant, pigment, filler, antitacking agent or antistatic agent, and is not included in the list of possible alkaline agents given elsewhere in the specification.

As further stated in the response, magnesium stearate is insoluble in ethanol, ether and water, hence cannot be defined as an alkaline agent, in contrast to sodium stearate

which is the alkalinizing agent of the instant application, such that the two cannot be considered functionally equivalent as alkalinizing agents.

Additionally, the examples referred to by the Examiner comprised omeprazole and not lansoprazole as active ingredient, which are not interchangeable.

With regard to obviousness, the Examiner stated that Depui '375 teaches a formulation which differs from that of the present invention only in that a surfactant and filler are present in the same layer as the active ingredient, while Ludberg discloses use of a surfactant in the subcoating layer of a formulation comprising a proton pump inhibitor. However, Depui '375 does not disclose magnesium stearate as being suitable for use as an alkaline agent in the separating layer, hence following the teaching of Depui '375 in combination with Ludberg would not result in the formulation of the present invention.

The Examiner also referred to Edgren, which discloses that potassium stearate, magnesium stearate and sodium stearate are functionally equivalent. However, the functional equivalence was taught in the context of use as lubricants and not as alkalinizing agents. No evidence is offered by the Examiner that magnesium stearate and sodium stearate are functionally equivalent as alkalinizing agents.

2. In a subsequent Office Action dated March 12, 2009, the Examiner rejected arguments that magnesium stearate and sodium stearate are not functionally equivalent as alkalinizing agents, referring again to the teaching of Edgren which states that the two stearates are functionally equivalent as lubricating agents.

Applicant again argued that it would not be obvious in view of the teachings of the equivalence of the stearates as lubricants to use sodium stearate instead of magnesium stearate as alkalinizing agent, which is an entirely different purpose, and further that the inclusion of the stearate in a subcoating layer is not taught in the prior art. Applicant submitted evidence in the form of pages from the US Pharmacopeia (attached herewith) showing the differences in solubility between the two stearates, which determine their ability to function as alkalinizing agents.

Furthermore, Applicant pointed out that according to the Webster online dictionary (http://www.websters-online-dictionary.org/definition/alkali), an alkali is

defined as 'any of various water-soluble compounds capable of turning litmus blue and reacting with an acid to form a salt and water', a printed copy of which is attached herewith. Thus, clearly magnesium stearate cannot be effective as an alkalizing agent; furthermore, none of the references cited by the Examiner or available to Applicant suggest that in fact magnesium stearate could be effective as an alkalizing agent.

3. In a further Office Action issued dated November 23, 2009, the Examiner maintains that since magnesium stearate and sodium stearate are disclosed as being functionally equivalent as lubricants, they are also functionally equivalent for the role of alkalinizing agents. The Examiner argued that stearates, which are taken as being functionally equivalent for one purpose may also be considered equivalent for an entirely different purpose, even though the Examiner acknowledges that the compounds would not be expected to have exactly the same properties.

As discussed above, in view of the low solubility of magnesium stearate in water and various organic solvents, this compound cannot be considered to function as an alkalinizing agent, in complete contrast to sodium stearate. Therefore the Examiner has failed to supply a reference supporting the claim rejections in this regard and has effectively argued that the rejections are "inherent" in the prior art cited, despite the Applicant's showing of references that demonstrate the opposite facts.

Overall, Applicant respectfully requests a Notice of Allowance indicating that the currently pending claims are allowable. Failing that, Applicant respectfully requests that the currently pending claims be returned to prosecution and the above issues addressed by the Examiner, in particular by providing specific, relevant references if in fact any such references exist; or alternatively, allowing the currently pending claims.

CONCLUSION

Applicant requests a Pre-Appeal Conference to address the above issues. If the Examiner believes that a telephonic interview with the undersigned would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned at (301) 952-1011.

Respectfully submitted,

/D'vorah Graeser, Reg No 40,000/

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 560

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on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/575,809	13 April 2006

First Named Inventor: Avi AVRAMOFF

Art Unit	Examiner
1618	WESTEBERG, Nissa M

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 40,000.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/D'vorah Graeser, Reg No 40,000/
Signature

Dvorah Graeser
Typed or printed name

301-952-1011
Telephone number

5-Feb-2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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